TSG Integrations
Div of Intelligent Instruments Pvt Ltd

K002132

202 Ashok Bhawan, 93 Nehru Place
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OCT 1 8 2001

SECTION E

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

E.1 APPLICANT:

Address: TSG Integrations
Division of Intelligent Instruments Private Limited
202 Ashok Bhawan, 93 Nehru Place
New Delhi – 110 019, INDIA

Tel: +91-11-6423266, 6420136
Fax: +91-11-6442728
Email: tsg@vsnl.com
Status: Developer & Manufacturer
Contact: S L Kapoor, Managing Director

E.2 DEVICE:

Trade Name: ASHA Treatment Planning System
Common Name: Radiotherapy Treatment Planning Computer
Classification Name: ACCELERATOR, LINEAR, MEDICAL
Product Code IYE

E.3 PREDICATE DEVICES:

510(k)	Model Name	Manufacturer
K911612	Nucletron Planning System	Nucletron Oldelft Corp.
K940237	Theraplan V05B/TP-11 V09B	Theratronics Inc.
K964167	Decision Support System	Multidata Systems International
K954679	Theraplan Plus	Theratronics Inc.

E.4 DEVICE DESCRIPTION:

ASHA Treatment Planning System is MS-Windows based medical software for planning teletherapy, brachytherapy and combined modalities of treatment. It includes the following components:

Teletherapy planning software uses multi-sectional CT / MR slice image data input through a film scanner. Scaling of patient image data and procedure for verification of dimensional accuracy is included. Network option allows image data to be acquired from

DICOM compliant image data source (CT/MR units). Image data is used to plan treatments in 3D volume of patient (dose is calculated in each transverse plane of a multi-sectional patient data) with a combination of photon and electron beams along with many types of beam modifiers. Software assists in conformal planning. Choice of 'dose calculation methods' are available. Dose is calculated based on measured data or using analytical models or using scatter integration technique or pencil beam model, with correction for oblique incidence and inhomogenieties in the patient. Dose is visualized on CT / MR images as well as on reconstructed sagital and coronal sections. Reconstructed Beam Eye View at any depth provides facility to verify the design of beam and absorbed dose. Relative dose (%) or absolute dose (cGy) are viewed based on user specified normalization scheme and dose prescription.

Brachytherapy planning software uses orthogonal radiographs image data input through film scanner. Software for verification of dimensional accuracy is included. Along with teletherapy planning, it also uses CT / MRI slice image data. Software supports Remote Afterloading applicators for HDR / MDR / LDR, applications for Intracavitory / Interstitial / Intraluminal / and surface moulds, and Prescription protocols as per Manchester / Paris or user specified scheme. The dose is visualized on radiographs, CT / MRI images or on any reconstructed cut sections. For any other orientation, the dose distribution is presented in empty space, along with selected anatomical points.

Combined teletherapy and brachytherapy software allows summation of teletherapy and brachytherapy dose for visualization. The dose is visualized on CT / MRI images on each slice or on any reconstructed cut sections.

Radiobiological support software is based on TDF and LQ models. The software calculates acute and late effects for a given fractionation scheme of treatment based on user specified LQ model parameters.

3D visualization Software is based on Virtual Reality Modeling of patient and other planning objects such as tumor, organs of interest, beams and iso-dose surfaces. The selected planning objects may be made transparent, partially transparent or opaque in any combination and in any orientation for perspective view. The patient can be virtually examined by changing the view and orientation as well as transparency of objects. Beam Eye View provides a 3D view through the beam showing the planning objects with desired transparency. This data may be transmitted to another site over the Web network for teleconsultation.

DICOM 3.0 compliance software provides output in DICOM RT objects of RT Image, RT Structure Set, RT Plan and RT Dose. At present media exchange or data exchange over the network (LAN) is supported.

Computer hardware consists of industry standard high end PC with MS-Windows operating system. Peripherals include film scanner, color printer, backup storage disk, network interface (LAN and WAN) and color monitor.

E.5 INDICATIONS FOR USE:

ASHA Treatment Planning System is a computer software based system for radiotherapy planning. It is intended to be used by qualified health care professionals to simulate, visualize and evaluate radiation dose distribution in the patient for a specified plan of radiation treatment. Many alternative plans may be evaluated with ease. The System supports teletherapy, brachytherapy and combined modalities of radiotherapy treatment. Radiobiology support is provided for fractionated and continuous radiation through the 'Linear Quadratic Model' with user specified parameters.

Radiation beam data for external beams and radiation source / applicator data for brachytherapy are provided by the user. This data is used for dose calculations. User has full control over this data in the library.

Patient data is in the form of CT / MR images and simulation radiographs of the volume of interest. This data is acquired in digital form (DICOM 3.0 compliant) in a network or through media exchange. It may also be acquired by scanning the film images using a Film Scanner. Delineation of the target volume, organs of interest and points of interest are done by the user on the acquired images through easy interaction on the computer screen.

The system can be used to plan for a range of treatment equipment namely, Medical Linear Accelerators (photons and electrons), Cobalt-60 Teletherapy units, and Remote Afterloading Brachytherapy units for HDR, MDR and LDR treatments. Absorbed dose distribution are computed and visualized in 2D / 3D. Selected plan of treatment is printed for documentation. The Plan may also be transferred to another device for Virtual Simulation of patient setup. Plan may be transmitted to another site using Web 3D Technology for Tele-consultation.

E.6 TECHNOLOGICAL CONSIDERATIONS:

ASHA Treatment Planning System software has no significant technological differences with regard to the concept, design, materials, energy source or other technological characteristics compared to the predicate devices.

E.7 CONCLUSION:

ASHA Treatment Planning System Version 2.0 software has been developed in compliance with Good Manufacturing Practice (GMP) applicable for software development activity. The developed software has been put through established procedures of in-house and hospital based testing and validation. These tests show that the System meets its published specifications, performs similar to the predicate devices to which is substantially equivalent and meets the claim of its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2001

Mr. S. L. Kapoor
Managing Director
TSG Intregrations
202 Ashok Bhawan
93 Nehru Place
NEW DELHI-110 019, INDIA

Re: K002132
Trade/Device Name: ASHA Treatment Planning System Release v2.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: October 1, 2001
Received: October 3, 2001

Dear Mr. Kapoor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002132

Device Name: ASHA Treatment Planning System Release 2.0

Indications For Use:

ASHA Radiotherapy Treatment Planning System is intended for 3D planning of external beams and brachytherapy. The System supports combined modalities of radiotherapy treatment. Radiobiology support is provided for fractionated and continuous radiation through the 'Linear Quadratic Model' with user specified parameters. Virtual simulation module provides facility to simulate the patient setup for beam marking.

The system can be used for a range of treatment units namely, Medical Linear Accelerators (photons and electrons), Cobalt-60 Teletherapy units, and Remote Afterloading Brachytherapy units for HDR, MDR and LDR treatments. Absorbed dose distributions are computed and visualized in 2D / 3D. Selected plan of treatment is printed for documentation.

S.L. Kapoor

(S L Kapoor)
Managing Director
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K002132

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801, 109)

(Optimal Format 1-2-96)